REMARKS

Applicants request reconsideration of the application in view of the above amendments and the following remarks.

Claim Amendments

Claims 1-2, 4-13, and 17-22 are pending in this application.

Claims 2, 3, 14-16, and 23-26 stand cancelled without prejudice or disclaimer.

Claim 1 is amended to recite that the microcatheter has a burst strength of from 700 to 1000 psi. No new matter is added by this amendment. Support for this amendment can be found, for example, in Claim 2 as previously presented. Claim 1 is also amended to recite that "the second layer gradually tapers to zero at the distal end wherein at least 3-5 cm of the distal end is provided with no polyimide." No new matter is added by this amendment. Support for this amendment can be found, for example, on page 6, paragraph [0034] and page 7, paragraph [0036] of the application as filed. The cancellation and amendment of the claims is not intended to be a dedication of the amended/cancelled subject matter to public. Applicants reserve the right to file one or more continuation applications directed to the amended/cancelled subject matter.

New Claim 27 is being added. No new matter is added by this new claim. Support for this new claim can be found on Example 2, pages 12-13 of the application as filed.

Entry of the amendment is respectfully requested.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, Claims 1, 4-13, 17-22, and 27 are now pending in this application.

Interview Summary

Applicants thank the Examiner, Laura A. Bouchelle and her Supervisor, Nicholas Lucchesi, for conducting a personal interview with the Applicants' representative, Gerald F. Swiss and Vandana Bansal, on June 19, 2008. In the interview, the pending Office Action; the pending claims 1-2, 4-13, and 17-22; and the art cited by the Examiner, were discussed. No agreement was reached regarding the pending claims and the art cited by the Examiner. No exhibit was shown nor a demonstration was conducted.

Claim Rejection under 35 U.S.C. §103(a)

Office has cited various references under this rejection all of which are as presented below:

1. Claims 1, 4-6, 11-13, and 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gore et al (US 5,662,622) in view of McGurk (US 5,676,659) and in view of Keith et al (US 6,841,214). Office alleges that Gore discloses a microcatheter comprising an inner layer formed of PTFE, a braided wire layer and an outer jacket; McGurk teaches the inner member being formed of a first lubricious layer formed of PTFE and a second outer layer formed of polyimide; and Keith teaches the pic rate of the wire reinforcement to be lower at the proximal end than at the distal end. *See* page 2, ¶3-5 of the Office Action.

2. Claims 11, 12, and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gore in view of McGurk and in view of Keith. The Office alleges that it would have been obvious to make a pic rate of the wire braid change continuosly or stepwise. *See* pages 3-4, ¶6 of the Office Action.

3. Claims 17-18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gore in view of McGurk. Office alleges that McGurk teaches that the outer jacket layer of the catheter comprises polyimide polyether block copolymer or nylon. *See* page 4, ¶7 of the Office Action.

4. Claim 2 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Gore in view of McGurk in view of Keith and further in view of Whalen et al (US 2002/0090339). Office alleges that Whalen teaches a microcatheter having a burst strength of at least 1000 psi. *See* pages 4-5, ¶8 of the Office Action.

5. Claims 7-8 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gore in view of McGurk in view of Keith and further in view of Scribner et al. (US 6,053,904). Office alleges that Scribner teaches a catheter system where the Braid comprises eight wires and also teaches that the wires have an elliptical cross section. *See* page 5, ¶9 of the Office Action.

6. Claims 9-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gore in view of McGurk in view of Keith and further in view of Pray et al. (US 5,533,987). Office alleges that Pray teaches a catheter with a braid having a pic rate at the most flexible end to be about 4 times that of the less flexible end. *See* page 5, ¶10 of the Office Action.

7. Claims 20-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gore in view of McGurk in view of Keith and further in view of Azam et al. (US 5,860,963). Office alleges that Azam teaches a catheter having an outer jacket having a durometer of 25 to 40 D. *See* page 6, ¶11 of the Office Action.

Office alleges that it would have been obvious to one of ordinary skill in the art to modify the device of Gore with the devices of the rest of the cited references to arrive at the claimed invention.

Applicants traverse each of these rejections for the following reasons.

First, solely to simplify prosecution, Applicants have included in Claim 1 the recitation of Claim 2 which provides that the claimed microcatheter have a burst strength of from 700 to 1000 psi and have further included the recitation that the inner layer comprises a first and second layer wherein the second layer comprises polyimide which gradually tapers to zero at the distal end such that at least 3-5 cm of the distal end is provided with no polyimide.

Second, as to now presented Claim 1, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) recently reviewed the analysis for determining if an invention is obvious over the teachings of the prior art and affirmed the factual analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966) Id. at 1734. The factual inquiries necessary in an analysis of obviousness by the Office is delineated in MPEP 2141:

> A) Determining the scope and contents of the prior art;
> (B) Ascertaining the differences between the prior art and the claims in issue;
> (C) Resolving the level of ordinary skill in the pertinent art; and
> (D) Evaluating evidence of secondary considerations

MPEP 2141 further states that:

> When applying 35 U.S.C. 103, ...
>
> (A) The claimed invention must be considered as a whole;
> (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
> (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
> (D) Reasonable expectation of success is the standard with which obviousness is determined.

This latter test, known as the teaching, suggestion and motivation (TSM) test for obviousness, was addressed by the Supreme Court in KSR, which confirmed that when such a test is applied with flexibility and in a non-mandatory manner, "[t]here is no inconsistency between the idea underlying the [teaching, suggestion, motivation] test and the Graham analysis.

Finally, for the following reasons, Applicants submit that the cited references either alone or in combination do not teach or suggest all the limitations of now presented Claim 1 and, accordingly, do not provide for a *prima facie case* of obviousness against the now claimed invention.

Applicants invention comprises of two rather conflicting features, namely, high flexibility and high burst strength. The microcatheter of the instant invention provides a higher degree of flexibility needed to traverse complicated small vessel pathways and higher degree of strength needed to withstand strenuous manipulation and the high pressures associated with catheter-delivery of viscous embolizing compositions. *See* page 3, paragraph [0011] of the application as filed. In the catheters of the invention, the three components, namely, the liner, the wire braid and the outer jacket are graduated in flexibility being more flexible at their distal end than at their proximal ends. *See* page 3, paragraph [0013] of the application as filed. This flexibility at the distal end and the stiffness at the proximal ends is achieved by providing a second layer of polyimide on the first layer of a lubricous polymer selected from the group consisting of polytetrafluoroethylene and high density polyethylenein such a way that the second layer of polyimide gradually tapers to zero at the distal end wherein at least 3-5 cm of the distal end is provided with no polyimide.

This is also illustrated in Figs. 5A-C of the application as filed (also shown below) where Fig. 5A shows a polyimide stiffening overliner present only on the proximal end of the liner; Fig. 5B showing the liner without overliner; and Fig. 5C showing the tapering in the overlay at its distal end. *See* page 4, paragraphs [0020], [0021], [0022], and [0023] of the application as filed.

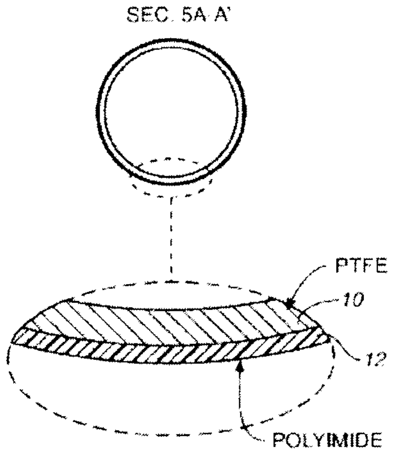

FIG._5A

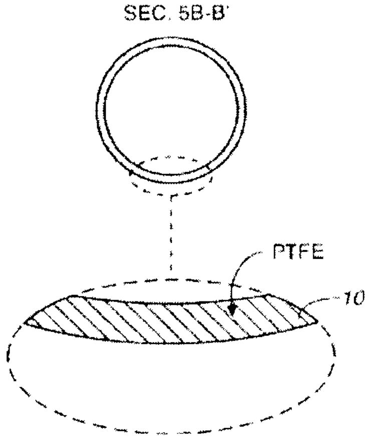

FIG._5B

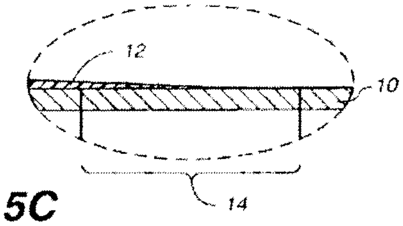

FIG._5C

This gradual tapering of the polyimide layer creates an inner liner having greater strength and reduced flexibility at the proximal end and greater flexibility and reduced strength at the distal end. *See* page 6, paragraph [0035] of the application as filed. This liner design combining a lubricious material and a strengthening material provides for additional burst strength for substantially the length of the catheter with the exception of the distal portion and provides lubricity throughout. *See* page 7, paragraph [0036] of the application as filed. Applicants further provide a Declaration from Earl Slee (**Exhibit I**) that shows that the gradual tapering to zero at the distal end of the polyimide layer which is on the first layer of a lubricous polymer selected from the group consisting of polytetrafluoroethylene and high density polyethylene, provides greater strength and reduced flexibility at the proximal end and greater flexibility and reduced strength at the distal end. The Declaration further shows that the greater strength imparts both proximal rigidity necessary for manipulation of the device as well as a greater burst strength necessary to permit viscous materials to be pushed through the lumen of the catheter.

Now in response to the Office Action, Applicants assert that none of the cited references teach or suggest a microcatheter comprising an inner layer consisting essentially of a first or inner polymer layer and a second or outer polymer layerwhere first polymer layer is a lubricous polymer selected from the group consisting of polytetrafluoroethylene and high density polyethylene andthe second layer comprises polyimide and wherein the second layer gradually tapers to zero at the distal end wherein at least 3-5 cm of the distal end is provided with no polyimide.

Office alleges that McGurk teaches the inner member being formed of a first lubricious layer formed of PTFE and a second outer layer formed of polyimide. However, such is simply not the case.

Reference by the Office to Col. 5, lines 54-67, of McGurk in the Office Action does not support this allegation. The specific language of McGurk in this cited section is as follows:

> In a preferred construction, the catheter body of the present invention will consist essentially of three structural components. The first component is an *inner tubular member which defines the inner lumen and provides a lubricious surface to receive the fluid or device which is to be introduced to a target location within the vasculature or other body lumen. Typically, the inner tubular member will be a sleeve formed from a single material, preferably a lubricious polymer, such as a fluorocarbon (e.g., polytetrafluoroethylene (PTFE)), a polyamide (e.g., nylon), a polyolefin, a polyimide, or the like.* It would also be possible to form the inner tubular members as a laminate structure comprising a non-lubricious outer layer and an inner lubricious layer or coating. (Emphasis added).

Note that the recitation of polyimide in this section of McGurk refers to the first polymer layer of a lubricous polymer and that the language of a laminate structure does not reference any polymer as the outer layer. In fact, McGurk teaches away from an outer polyimide layer as McGurk specifically recites that the inner layer is a lubricous polymer such as a polyimide layer while the outer layer is a non-lubricous layer. Since polyimide is recited by McGurk as a lubricous polymer, the explicit teachings of McGurk would teach away from using it as the outer layer polymer.

Nor is there any reference in McGurk that the second layer (regardless of its polymer makeup) should gradually tapers to zero at the distal end such that at least 3-5 cm of the distal end is provided with no second layer. Since none of the cited references either alone or in combination disclose all the claim limitations, the *prima facie* case of obviousness is not established.

Further, none of the cited references suggest or motivate a person of ordinary skill in the art to taper the polyimide layer towards the distal end wherein at least 3-5 cm of the distal end is not provided with any polyimide. Furthermore, there is no reasonable expectation of success that the tapering of the polyimide layer towards the distal end wherein at least 3-5 cm of the distal end is not provided with any polyimide would result in high flexibility coupled with high strength, as in the claimed invention.

In view of the reasons as provided above, withdrawal of this rejection under 35 U.S.C. §103(a) is respectfully requested.

As Applicants submit that independent Claim 1 is non-obvious over the cited art, Applicants further submit that the rejections of the dependent claims set forth above are now moot. Withdrawal of these further rejections is requested.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

CONCLUSION

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date August 19, 2008

By Gerald F. Swiss

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1103
Facsimile: (650) 856-3710

Gerald F. Swiss
Attorney for Applicants
Registration No. 30,113